

Claims

We claim:

1. A composition for modulating the immune response in a subject comprising a mutein of interleukin-1 (IL-1) having reduced toxicity to a human compared to the corresponding wild-type IL-1.
2. The composition according to claim 1, wherein said IL-1 is IL-1 $\beta$ .
3. The composition according to claim 1, wherein said IL-1 is mature IL-1 $\beta$ .
4. The composition according to claim 1, wherein said IL-1 is human IL-1.
5. The composition according to claim 1, wherein a positively charged residue of said IL-1 has been replaced with any of the other 17 natural amino acids.
6. The composition according to claim 5, wherein said positively charged residue is arginine or lysine.
7. The composition according to claim 6, wherein said IL-1 is mature human IL-1 $\beta$  and wherein said positively charged residue replaced is arginine at position 127.

8. A method of modulating the immune response of a subject to a vaccine antigen comprising administering an effective amount of interleukin-1 (IL-1) mutein having reduced toxicity, in concurrent or sequential combination with said vaccine antigen.
9. The method according to claim 8, wherein said IL-1 is IL-1 $\beta$ .
9. The method according to claim 8, wherein said IL-1 is IL-1 $\beta$ .
10. The method according to claim 8, wherein said IL-1 is mature IL-1 $\beta$ .
11. The method according to claim 8, wherein said IL-1 is human IL-1 $\beta$ .
12. The method according to claim 8, wherein a positively charged residue of said IL-1 has been replaced with any of the other 17 natural amino acids.
13. The method according to claim 12, wherein said positively charged residue is arginine or lysine.
14. The method according to claim 13, wherein said IL-1 is mature human IL-1 $\beta$  and wherein said positively charged residue replaced is arginine at position 127.
15. The method according to claim 8, wherein said vaccine antigen is selected from the group consisting of proteins, peptides, hormones and glycoproteins.

16. The method according to claim 8, wherein said vaccine antigen is selected from the group consisting of viral antigen, fungal antigen, parasitic antigen, bacterial antigen, allergen, auto-immune related antigen and tumor-associated antigen.

17. The method according to claim 8, wherein said IL-1 mutein is administered by a method selected from the group consisting of mucosally, intramuscularly and subcutaneously.

18. The method according to claim 8, wherein said IL-1 mutein is administered in a pharmaceutically acceptable vehicle.

19. The method according to claim 8, wherein said subject is a vertebrate.

20. The method according to claim 8, wherein said subject is human.